CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences
Higher Diploma in Pharmaceutical and Cosmetic Sciences
HD 2143 Maintenance Sciences
Batch 02
2nd Year 1st Semester
End Semester Examination – SEQ

INDEX NUMBER: .....

Date : 22nd July 2024
Time : 9.00 a.m. - 12.00 p.m. (Three hours)

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** the questions on this paper itself.
- Final answers should be given legibly in black or blue ink.

Question 01 **(100 marks)**

1.1 List **02** types of utilities used in the pharmaceutical industry. (10 marks)

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1.2 State **02** pharmaceutical industry specific key maintenance practices. (20 marks)

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1.3 List the least mature and the most mature types of maintenance. (10 marks)

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1.4 Describe the importance of each type of maintenance mentioned in 1.3 above. (30 marks)

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1.5 Describe how to handle overdue preventive maintenance of a machine. (30 marks)

Question 02 **(100 marks)**

2.1 How do validation and maintenance interconnect in the pharmaceutical industry? (15 marks)

2.2 State **04** types of validation used in the pharmaceutical industry. (20 marks)

2.3 Briefly discuss the importance of a validation master plan. (20 marks)

2.4 Differentiate operational and performance qualifications. (20 marks)

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2.5 What is the process of 'installation qualification'. (25 marks)

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Question 03 **(100 marks)**

3.1 Define the term 'preventive maintenance'. (15 marks)

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3.2 What are the advanced criteria to define frequencies in a maintenance schedule? (20 marks)

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3.3 List **02** advantages and **02** disadvantages of preventive maintenance. (20 marks)

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3.4 Briefly describe the asset identification in maintenance schedule. (20 marks)

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3.5 Write a short note on the process of machine handover in a manufacturing plant. (25 marks)

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Question 04 **(100 marks)**

4.1 Define the term 'machine breakdown'. (25 marks)

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4.2 List **02** causes each for 'run to failure maintenance' and 'emergency breakdown maintenance' in the pharmaceutical industry. (25 marks)

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4.3. State **05** actions that can be taken to effectively manage breakdown maintenance. (25 marks)

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4.4 Mention **05** types of facilities considered under facility maintenance. (25 marks)

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Question 05 **(100 marks)**

5.1 List **03** criteria that maintenance equipment should fulfill. (25 marks)

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5.2 What is meant by 'spare parts' in relation to maintenance science? (25 marks)

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5.3 List **04** considerations you should take into account upon receiving new GxP and EHS critical spare parts in the pharmaceutical industry. (25 marks)

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5.4 Write a short note on GxP lubricants. (25 marks)

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Question 06 **(100 marks)**

6.1 List **03** types of maintenance related risk assessment. (30 marks)

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6.2 State **04** observations you should make during risk assessment. (35 marks)

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6.3 Write the importance of risk assessment in cosmetic industry. (35 marks)

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CINEC CAMPUS
Beyond A Graduate

Faculty of Health Sciences

Higher Diploma in Pharmaceutical & Cosmetic Sciences

HD 2133 - Pharmaceutical & Cosmeceutical Packaging

Batch - 02

2nd Year 1st semester

End Semester SEQ Examination

INDEX NUMBER: .....

Date : **19th July 2024**
Time : **9.00 a.m. – 12.00 p.m. (Three Hours)**

INSTRUCTIONS TO CANDIDATES

- This question paper consists of **SIX** questions.
- Answer **ALL** questions.
- You should write legibly in black or blue ink.
- You are not allowed to take out the examination papers.

01 **(100 marks)**

1.1. Write **04** selection criteria of pharmaceutical packaging. (20 marks)

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1.2. State **05** ideal pharmaceutical packaging requirements. (20 marks)

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1.3. Describe the main **03** types of pharmaceutical packaging by providing examples for each. (30 marks)

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1.4. State **05** advantages and disadvantages of glass as a pharmaceutical packaging material. (30 marks)

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02 **(100 marks)**

2.1. Define pharmaceutical label reconciliation. (10 marks)

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2.2. Write the advantages of label reconciliation in related to pharmaceutical industry. (25 marks)

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2.3. "Knowing what the labels and their packaging are made of will help in ensuring the disposing of them in a responsible and environmentally friendly manner."
Based on this statement outline the structure of a pharmaceutical label that help understanding the proper disposal practice. (30 marks)

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2.3. State **03** legal requirements of a manufacturer label and describe them. (35 marks)

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03 **(100 marks)**

3.1. What are desiccants? (20 marks)

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3.2. List two reasons to use desiccants in pharmaceutical packaging? (20 marks)

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3.3. State how montmorillonite clay is used as a desiccant in the pharmaceutical industry. (30 marks)

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3.4. "The primary and secondary packaging materials should pass the quality control tests before they are issued for the packaging process." Comment on this statement.

(30 marks)

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04 **(100 marks)**

4.1. Write the process of line clearance in pharmaceutical packaging.

(30 marks)

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4.2. State **05** general tests conduct to access the quality of pharmaceutical glass containers. (30 marks)

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4.3. Briefly describe the following test which is carried out for finished pharmaceutical products.

4.3.1. Carton drop test. (40 marks)

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05 **(100 marks)**

5.1. List 02 types of tamper resistant packages. (20 marks)

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5.2. "Blister packaging is favored by pharmaceutical companies". Justify this statement giving 04 reasons. (40 marks)

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5.3. What is meant by thermoforming? (40 marks)

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06 **(100 marks)**

6.1. List 03 types of film wrappings used in pharmaceutical and cosmeceutical industry. (40 marks)

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6.2. What are the commonly used materials for film wrapping? (20 marks)

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6.3. Outline the mechanism used in photoelectric cell counters in tablet/capsule counting. (40 marks)

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